10

15

20

25

30

CEN0285

WHAT IS CLAIMED IS:

- 1. An isolated RELP protein human Ig derived protein or specified portion or variant, comprising a human variable and human constant region, wherein said human Ig derived protein or specified portion or variant specifically binds at least one epitope comprising at least 1-3, to the entire amino acid sequence, selected from the group consisting of SEQ ID NOS: 2, 4, 5, 6, 7, 8, 9, 10 and/or 11.
- 2. An RELP protein human Ig derived protein or specified portion or variant according to claim 65, wherein said human Ig derived protein or specified portion or variant binds RELP protein with an affinity of at least 10⁻⁹ M.
- 3. An RELP protein human Ig derived protein or specified portion or variant according to claim 65, wherein said human Ig derived protein or specified portion or variant binds RELP protein with an affinity of at least 10⁻¹¹ M.
- 4. An RELP protein human Ig derived protein or specified portion or variant, according to claim 65, wherein said human Ig derived protein or specified portion or variant binds with an affinity of at least 10^{-12} M.
- 5. An RELP protein human Ig derived protein or specified portion or variant according to claim 65, wherein said human Ig derived protein or specified portion or variant substantially neutralizes at least one activity of at least one RELP protein.
- 6. An isolated RELP protein human Ig derived protein encoding nucleic acid, comprising a nucleic acid that encodes an RELP Ig derived protein according to claim 1.
- 7. An isolated RELP protein human Ig derived protein or specified portion or variant, comprising an isolated human Ig derived protein or specified portion or variant encoded by a nucleic acid according to claim 6.
- 8. An RELP protein human Ig derived protein encoding nucleic acid composition, comprising an isolated nucleic acid according to claim 6 and a carrier or diluent.
- 9. A human Ig derived protein vector, comprising a nucleic acid according to claim 6.
- 10. A human Ig derived protein vector according to claim 9, wherein said vector comprises at least one promoter selected from the group consisting of a late or early SV40 promoter, a CMV promoter, an HSV tk promoter, a pgk (phosphoglycerate kinase) promoter, a human immunoglobulin promoter, or an EF-1 alpha promoter.
- 11. A human Ig derived protein vector according to claim 9, wherein said vector comprises at least one selection gene or portion thereof selected from at least one of

10

15

20

25

30

methotrexate (MTX), dihydrofolate reductase (DHFR), green fluorescent protein (GFP), neomycin (G418), or glutamine synthetase (GS).

- 12. A mammalian host cell comprising an isolated nucleic acid according to claim 6.
- 13. A host cell according to claim 12, wherein said host cell is at least one selected from COS-1, COS-7, HEK293, BHK21, CHO, BSC-1, Hep G2, 653, SP2/0, 293, HeLa, myeloma, or lymphoma cells, or any derivative, immortalized or transformed cell thereof.
 - 14. A method for producing at least one RELP protein human Ig derived protein or specified portion or variant, comprising translating a nucleic acid according to claim 6 or an endogenous nucleic acid that hybridizes thereto under stringent conditions, under conditions in vitro, in vivo or in situ, such that the RELP protein human Ig derived protein or specified portion or variant is expressed in detectable or recoverable amounts.
 - 15. An RELP protein human Ig derived protein or specified portion or variant composition, comprising at least one isolated RELP protein human Ig derived protein or specified portion or variant according to claim 1, and a carrier or diluent.
 - 16. A composition according to claim 15, wherein said carrier or diluent is pharmaceutically acceptable.
 - A composition according to claim 15, further comprising at least one compound or protein selected from at least one of a TNF antagonist, an antirheumatic, a muscle relaxant, a narcotic, a non-steroid anti-inflammatory drug (NSAID), an analgesic, an anesthetic, a sedative, a local anethetic, a neuromuscular blocker, an antimicrobial, an antipsoriatic, a corticosteriod, an anabolic steroid, a diabetes related agent, a mineral, a nutritional, a thyroid agent, a vitamin, a calcium related hormone, an antidiarrheal, an antitussive, an antiemetic, an antiulcer, a laxative, an anticoagulant, an erythropieitin, a filgrastim, a sargramostim, an immunization, an immunoglobulin, an immunosuppressive, a growth hormone, a hormone replacement drug, an estrogen receptor modulator, a mydriatic, a cycloplegic, an alkylating agent, an antimetabolite, a mitotic inhibitor, a radiopharmaceutical, an antidepressant, antimanic agent, an antipsychotic, an anxiolytic, a hypnotic, a sympathomimetic, a stimulant, donepezil, tacrine, an asthma medication, a beta agonist, an inhaled steroid, a leukotriene inhibitor, a methylxanthine, a cromolyn, an epinephrine or analog, dornase alpha, a cytokine, a cytokine antagonist.
 - 18. A method for treating a malignant condition or disease condition in a cell, tissue, organ or animal, comprising
 - (a) contacting or administering a selected malignant condition or disease modulating

10

15

20

25

a human.

effective amount of at least one RELP protein human Ig derived protein or specified portion or variant according to claim 65 with, or to, said cell, tissue, organ or animal.

- 19. A method according to claim 18, wherein said animal is a primate.
- 20. A method according to claim 19, wherein said primate is a monkey or
- 21. A method according to claim 18, wherein said malignant condition or disease is at least one selected from .
- 22. A method according to claim 18, wherein said effective amount is 0.001-50 mg/kilogram of said cells, tissue, organ or animal.
- 23. A method according to claim 18, wherein said contacting or said administrating is by at least one mode selected from intravenous, intramuscular, bolus, intraperitoneal, subcutaneous, respiratory, inhalation, nasal, vaginal, rectal, buccal, sublingual, intranasal, subdermal, or transdermal.
- A method according to claim 18, further comprising administering, 24. prior, concurrently or after said (a) contacting or administering, at least one composition comprising a therapeutically effective amount of at least one compound or protein selected from at least one of a TNF antagonist, an antirheumatic, a muscle relaxant, a narcotic, a nonsteroid anti-inflammatory drug (NSAID), an analgesic, an anesthetic, a sedative, a local anethetic, a neuromuscular blocker, an antimicrobial, an antipsoriatic, a corticosteriod, an anabolic steroid, a diabetes related agent, a mineral, a nutritional, a thyroid agent, a vitamin, a calcium related hormone, an antidiarrheal, an antitussive, an antiemetic, an antiulcer, a laxative, an anticoagulant, an erythropieitin, a filgrastim, a sargramostim, an immunization, an immunoglobulin, an immunosuppressive, a growth hormone, a hormone replacement drug, an estrogen receptor modulator, a mydriatic, a cycloplegic, an alkylating agent, an antimetabolite, a mitotic inhibitor, a radiopharmaceutical, an antidepressant, antimanic agent, an antipsychotic, an anxiolytic, a hypnotic, a sympathomimetic, a stimulant, donepezil, tacrine, an asthma medication, a beta agonist, an inhaled steroid, a leukotriene inhibitor, a methylxanthine, a cromolyn, an epinephrine or analog, dornase alpha, a cytokine, a cytokine antagonist.
- derived protein or specified portion or variant according to claim 1, wherein said device is suitable to contacting or administerting said at least one RELP protein human Ig derived protein or specified portion or variant by at least one mode selected from intravenous, intramuscular, bolus, intraperitoneal, subcutaneous, respiratory, inhalation, nasal, vaginal,

10

15

20

rectal, buccal, sublingual, intranasal, subdermal, or transdermal.

- 26. A human immunoglobulin light chain RELP protein or portion thereof, comprising at least one portion of a variable region comprising at least one human Ig derived protein fragment according to claim 1.
- 27. A human immunoglobulin heavy chain or portion thereof, comprising at least one portion of a variable region comprising at least one RELP protein human Ig derived protein fragment according to claim 1.
 - 28. A human Ig derived protein or specified portion or variant thereof, wherein said human Ig derived protein or specified portion or variant binds the same epitope or antigenic region as a RELP protein human Ig derived protein or specified portion or variant according to claim 1.
 - 29. A formulation comprising at least one RELP protein human Ig derived protein or specified portion or variant according to claim 1, and at least one selected from sterile water, sterile buffered water, or at least one preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thimerosal, or mixtures thereof in an aqueous diluent.
 - 30. A formulation of Claim 29, wherein the concentration of RELP protein human Ig derived protein or specified portion or variant is about 0.1 mg/ml to about 100 mg/ml.
 - 31. A formulation of Claim 29, further comprising an isotonicity agent.
 - 32. A formulation of Claim 29, further comprising a physiologically acceptable buffer.
- protein or specified portion or variant according to Claim 1 in lyophilized form in a first container, and an optional second container comprising at least one of sterile water, sterile buffered water, or at least one preservative selected from the group consisting of phenol, m-cresol, p-cresol, o-cresol, chlorocresol, benzyl alcohol, alkylparaben, benzalkonium chloride, benzethonium chloride, sodium dehydroacetate and thimerosal, or mixtures thereof in an aqueous diluent.
 - 34. A formulation of Claim 33, wherein the concentration of RELP protein human Ig derived protein or specified portion or variant is reconstituted to a concentration of about 0.1 mg/ml to about 500 mg/ml.
 - 35. A formulation of Claim 33, further comprising an isotonicity agent.

10

15

20

25

30

- 36. A formulation of Claim 33, further comprising a physiologically acceptable buffer.
- 37. A method of treating at least one RELP protein mediated condition, comprising administering to a patient in need thereof a formulation according to Claim 29.
- 38. A method of treating at least one RELP protein mediated condition, comprising administering to a patient in need thereof a formulation according to Claim 33.
- 39. An article of manufacture for human pharmaceutical use, comprising packaging material and a container comprising a solution or a lyophilized form of at least one RELP protein human Ig derived protein or specified portion or variant according to claim 1.
- 40. The article of manufacture of Claim 39, wherein said container is a glass or plastic container having a stopper for multi-use administration.
- 41. The article of manufacture of Claim 39, wherein said container is a blister pack, capable of being punctured and used in intravenous, intramuscular, bolus, intraperitoneal, subcutaneous, respiratory, inhalation, nasal, vaginal, rectal, buccal, sublingual, intranasal, subdermal, or transdermal administration.
- 42. The article of manufacture of claim 39, wherein said container is a component of a intravenous, intramuscular, bolus, intraperitoneal, subcutaneous, respiratory, inhalation, nasal, vaginal, rectal, buccal, sublingual, intranasal, subdermal, or transdermal delivery device or system.
- 43. The article of manufacture of Claim 39, wherein said container is a component of an injector or pen-injector device or system for intravenous, intramuscular, bolus, intraperitoneal, subcutaneous, respiratory, inhalation, nasal, vaginal, rectal, buccal, sublingual, intranasal, subdermal, or transdermal.
- 44. A method for preparing a formulation of at least one RELP protein human Ig derived protein or specified portion or variant, comprising admixing at least one RELP protein human Ig derived protein or specified portion or variant according to claim 1 in at least one buffer containing saline or a salt.
- 45. A method for producing at least one RELP protein human Ig derived protein or specified portion or variant according to claim 1, comprising providing a host cell, transgenic animal, transgenic plant or plant cell capable of expressing in recoverable amounts said human Ig derived protein or specified portion or variant.
- 46. A method according to claim 45, wherein said host cell is a mammalian cell, a plant cell or a yeast cell.
 - 47. A method according to claim 45, wherein said transgenic animal is a

mammal.

5

10

15

20

25

30

- 48. A method according to claim 47, wherein said transgenic mammal is selected from a goat, a cow, a sheep, a horse, and a non-human primate.
- 49. A transgenic animal or plant expressing at least one human Ig derived protein according to claim 1.
- 50. At least one RELP protein human Ig derived protein or specified portion or variant produced by a method according to claim 45.
- 51. A method for treating at least one RELP protein mediated disorder, comprising
 - (a) administering an effective amount of a composition or pharmaceutical composition comprising at least one RELP protein human Ig derived protein or specified portion or variant to a cell, tissue, organ, animal or patient in need of such modulation, treatment or therapy; and
 - (b) further administering, before concurrently, and/or after said administering in (a) above, at least one selected from at least one TNF antagonist, an antirheumatic, a muscle relaxant, a narcotic, a non-steroid antiinflammatory drug (NSAID), an analgesic, an anesthetic, a sedative, a local anethetic, a neuromuscular blocker, an antimicrobial, an antipsoriatic, a corticosteriod, an anabolic steroid, a diabetes related agent, a mineral, a nutritional, a thyroid agent, a vitamin, a calcium related hormone, an antidiarrheal, an antitussive, an antiemetic, an antiulcer, a laxative, an anticoagulant, an erythropoietin, a filgrastim, a sargramostim, an immunizing agent, an immunoglobulin, an immunosuppressive, a growth hormone, a hormone replacement drug, an estrogen receptor modulator, a mydriatic, a cycloplegic, an alkylating agent, an antimetabolite, a mitotic inhibitor, a radiopharmaceutical, an antidepressant, antimanic agent, an antipsychotic, an anxiolytic, a hypnotic, a sympathomimetic, a stimulant, adonepezil, a tacrine, an asthma medication, a beta agonist, an inhaled steroid, a leukotriene inhibitor, a methylxanthine, a cromolyn, an epinephrine or analog, a dornase alpha, or a cytokine, a cytokine antagonist.
- 52. An RELP protein human Ig derived protein or specified portion or variant, wherein said human Ig derived protein or specified portion or variant binds RELP protein with an affinity of at least 10-9 M.

- 53. An RELP protein human Ig derived protein or specified portion or variant according to claim 52, wherein said human Ig derived protein or specified portion or variant binds RELP protein with an affinity of at least 10^{-11} M.
- 54. An RELP protein human Ig derived protein or specified portion or variant, according to claim 53, wherein said human Ig derived protein or specified portion or variant binds with an affinity of at least 10⁻¹² M.
 - 55. Any invention described herein.